Data Sharing: The Road Ahead
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Agenda
• Future of Data Sharing > Roadmap Introduced Last Year
• What We Delivered On
• Where We Will Focus in 2016: The Road Ahead
• Asking for Your Input (Roundtable Discussion)

Transforming Data into Knowledge

Data Sharing Vision
• We envision a future in which...
  – CIBMTR is sharing data, information and knowledge with all stakeholders, with increase speed, increased quality
  – CIBMTR is able to accommodate more studies each year
  – CIBMTR provides better, more closely-tailored service to the TCs and the network at large, via user friendly, purpose-focused apps
  – CIBMTR’s systems, processes, and technologies are resilient, nimble, and responsive to:
    • evolving needs of stakeholders,
    • increased requests for information and
    • changes in medicine

Ingredients for Our Future Success
• Quality Data
• Quality Methods
• Quality People
• Adapt quickly to changes in medicine & technology
• Do more with less
• Increase productivity through use of technology
• Make more data available in more ways:
  - Visualization
  - Interactivity
  - On-demand, self-service access
• Make data available rapidly
• Reduce time from capture to:
  - Availability
  - Analysis
  - Publication
• Adapt quickly to changes in medicine & technology

Future State CIBMTR Research Data Life Cycle:
the Integrated Data Warehouse (IDW)
Inside the Data Warehouse

Matching Product Offerings to Your Needs

2015 Highlights: Quality Data (cont’d)

2015 Highlights: Quality Data Impact
2015 Highlights: Impacts on Analyses

- **Center Volumes**

<table>
<thead>
<tr>
<th></th>
<th>Data Discrepancies in 2013</th>
<th>Data Discrepancies in 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>493</td>
<td>115</td>
</tr>
<tr>
<td>Disease</td>
<td>92</td>
<td>19</td>
</tr>
<tr>
<td>Donor</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>

- **Center Specific Analysis**

<table>
<thead>
<tr>
<th></th>
<th>2014 Analysis</th>
<th>2015 Analysis (tentative)</th>
<th>2016 Analysis (tentative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRIDs with Data Issue</td>
<td>2357</td>
<td>2066 (+449)</td>
<td>119 (-3206)</td>
</tr>
<tr>
<td>Data issues identified by DQT</td>
<td>6114</td>
<td>4439 (-1675)</td>
<td>595 (-3844)</td>
</tr>
</tbody>
</table>

2015 Highlights: Analytics

- **Business Intelligence**
  - Establishment of business intelligence application platform
  - QlikView
    - Development of two business intelligence applications
    - Enhanced Data Back to Centers App
    - Transplant Center Specific Analysis App

2016 Focus

- **Establishment of Unified Domain**
  - Single Version of the Truth
- **Establishment of TC User Group**
  - Focused on Business Intelligence (BI)
  - Identification, prioritization and requirements of BI apps
- **Implementation or expansion of high priority Business Intelligence applications**
- **Expansion of data quality workflows and applications**
- **Metadata Management**
- **Cellular Therapy**

Objective of CIBMTR Cellular Therapy Initiative

- To study therapies using cellular products for indications other than hematopoietic replacement or recovery.
- To **provide an infrastructure** to allow long-term follow-up of patients treated with cellular therapy products.

CIBMTR Cellular Therapy Registry

- Prioritize certain **indications** for CRFs:
  - Malignancies (ALL, CLL and others)
  - Infections (Viral infections)
- Prioritize certain **products** for CRFs:
  - Genetically modified cells
    - Chimeric antigen receptors (CARs) for malignancy
    - Multi-virus-specific T-cells for infection
  - But capture any cell therapy that is not a transplant
    - Including Donor Cellular Infusions (DCIs)

Model for the Cellular Therapy Registry
Basic Model for Collection of all Cellular Therapies

For All Planned Infusions

Pre-CTED 4000 → Post-CTED 4100

Infusion Form 4006 → New Infusions 4006

3m, 6m, 1y and yearly thereafter

For All Infusions Given: since the last form

Cellular Therapy Scenarios

• Several scenarios for which we need to collect data
  – Cellular therapy only
    • Regenerative medicine
    • CAR T-cells for malignancy
    • CTL for infection
  – Co-infusions: HCT plus cellular therapy
  – Sequential cellular therapies for same/different indications
  – Cellular therapy followed by HCT (e.g. bridge to HCT)
  – HCT followed by cellular therapy (e.g. DCI)

Important Issues to Address for Long-term Follow-up of Cellular Therapy

• Ability to capture all patients / variables of interest
• Ensuring data quality
• Maintaining long-term follow-up
• Ensuring confidentiality, security and regulatory compliance
• Making data rapidly available for multiple users / uses
• Cost-effectiveness

Data Collection Approach

• Leverage existing infrastructure, where possible
• Design / build forms in FN
• Pilot data collection at different centers in patients receiving diverse products for diverse indications
• Data collection at centers:
  – Important to include cell processing laboratory;
  – Multiple programs (including HCT program) at a single center

Data Storage & Extraction

• Establish embargo rules that would control release of outcome data for IND/IDE protocols until agreed upon milestone
• Support feedback loop to assess whether the correct data is being captured
• Implement Data Back to Centers functionality for CT

Cellular Therapy Registry Status

✓ CTED level forms are completed and designed
• Planned release in FormsNet in Summer 2016
• CRF level forms under development
• Next steps:
  – Harmonization with EBMT
  – Develop a protocol for collection of long-term follow-up data for genetically modified cells
Asking for Your Input

• Input and Engagement
  – 2014 Site visits and engagement at the Tandem meeting(s) are helpful, but we need continued engagement to produce the best possible products...

• Roundtable Discussion(s)
  – Aligning our focus with Center data needs
  – Enhancing how you use data
  – How best to structure center participation